Model NCI-480
Water Caloric Stimulator

Operator's Manual

ICS medical

ADVANCING THE SCIENCE OF VESTIBULAR DIAGNOSTICS

NCI-480

WATER CALORIC STIMULATOR

Operator's Manual

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FORWARD

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TABLE OF CONTENTS

Section		Page
I.	Introduction	1
II.	Installation	3
	A) Placement	3
	B) Room Conditions	5
	C) Interconnections	5
	D) Charging the Memory Backup Capacitor	5
III.	Operation	6
	A) Front Panel Controls	8
	B) Rear Panel Connectors	10
	C) The Delivery Head Controls	13
IV.	Operating Procedures	15
	A) Preparation for Testing	15
	B) Testing Procedure	16
V.	Safety Features	16
VI.	Maintenance	18
VII.	Warranty	19
VIII.	Specifications	20

I. INTRODUCTION

The NCI-480 Water Caloric Stimulator delivers a thermal stimulus to the inner ear for vestibular testing.

In order to meet the requirements of a caloric test, it delivers the most precise, repeatable stimulus available. By continuously circulating the water through the delivery tube, the water temperature reaches a steady state and the need to purge is eliminated. The rate at which heat is lost to the delivery tubing and the surrounding environment is constant, avoiding the problem of changing rates of heat loss in systems that do not continuously recirculate the water.

The system consists of two independent temperature-controlled baths inter-connected to a common delivery system. These baths will maintain separate temperatures within ± 0.1°C of their preset temperature. The bath containers are designed to resist spillage and to be easy to remove and replace.

The temperature and duration of the stimulus are set using a digital control on the front panel. A separate control on the front panel allows the operator to set and measure the flow rate. Powerful pumps assure that the height of the delivery head does not significantly change the flow rate.

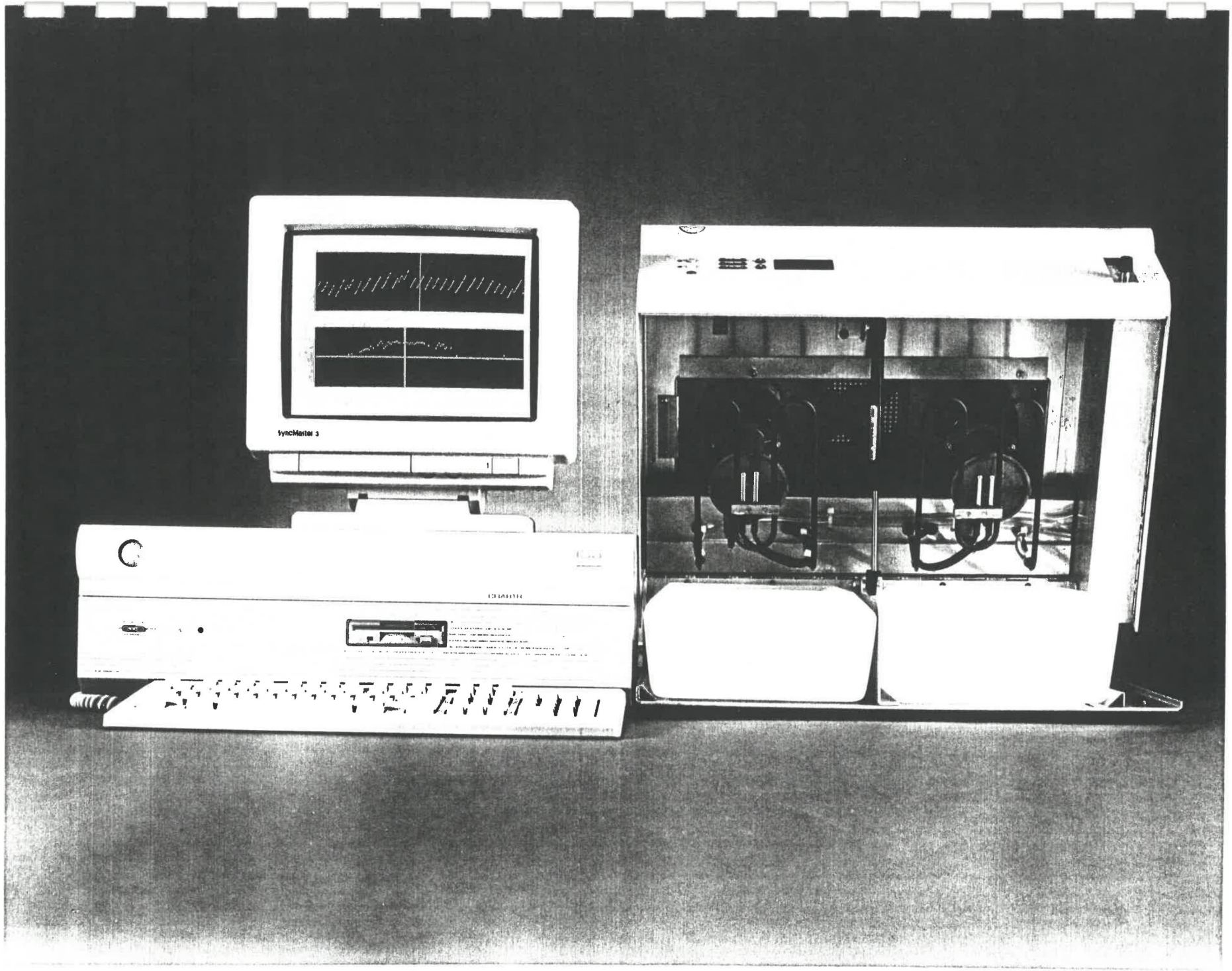

Figure 1: Front view of unit with chassis tilted upward.

II. INSTALLATION

Carefully unpack the unit and remove it from the box. Place it on a flat surface for examination. Remove the two knurled shipping screws from the bottom front of the unit. Tilt the chassis upward (Fig 1). The support mechanism will hold the hinged chassis in the open position. Check the bath containers to be sure they are clean and free of anything that might inhibit operation.

A. Placement

The system is designed to be used at any convenient level such as on a table or cart. A 2'h x 2'w x 2'd area is required. The water-filled weight of this unit is approximately 65 pounds which must be considered in its installation on a load-bearing surface. A typical room layout is shown in Figure 2.

Location of the system near a sink with running water is recommended to facilitate emptying and cleaning processes. **Note that distilled water must be used for irrigations.** Water that is not distilled will leave deposits of mineral and/or metallic salts in the miniature solenoid control valves.

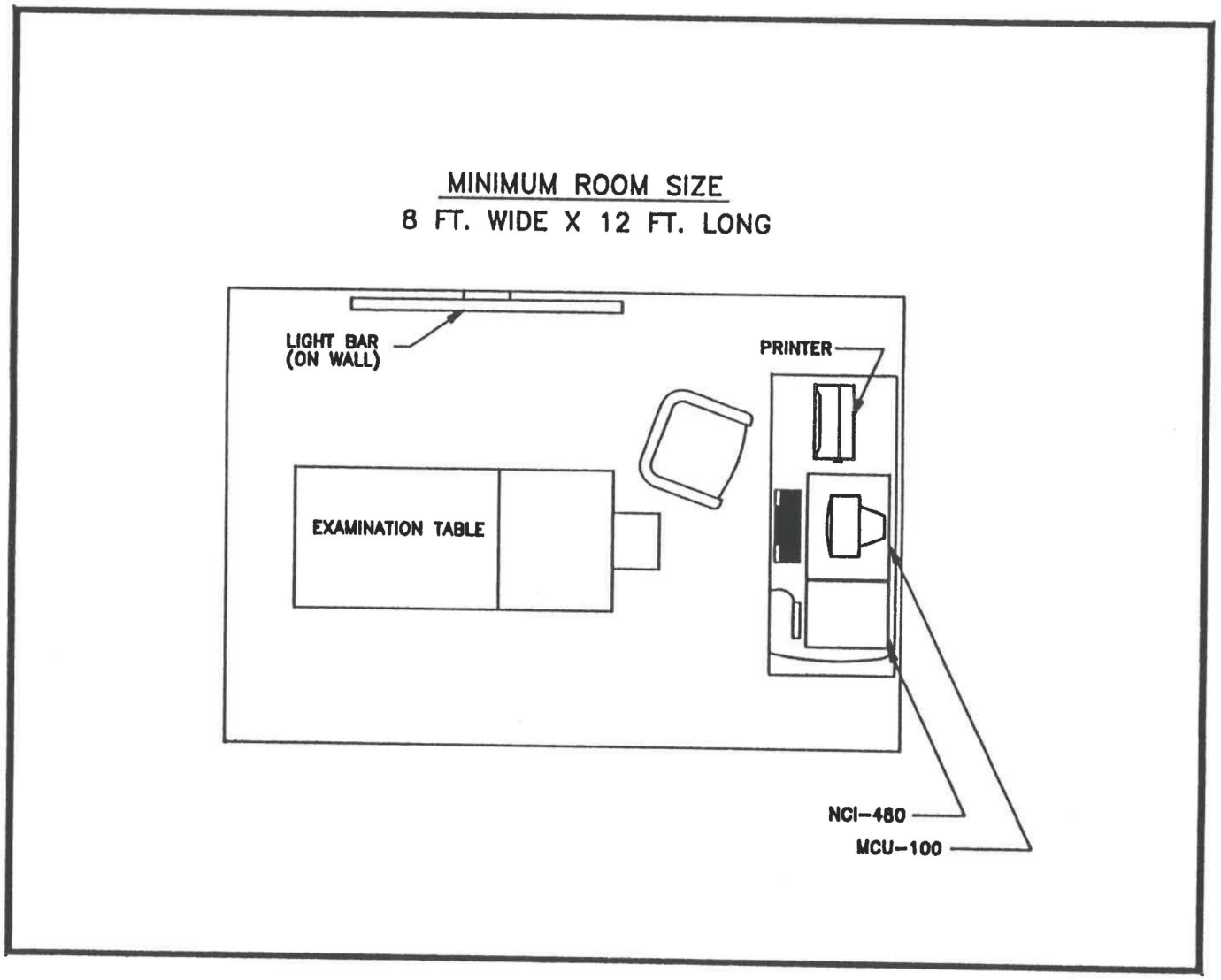

Figure 2: Typical Room layout for performing the ENG Test.

B. Room Conditions

It is important for the most convenient operation of this system that the room temperature remain at or below 24°C. This is almost always possible in normal air-conditioned examining rooms. Temperatures above this value will cause the 30°C bath to take significant time to cool to 30°C when the bath is switched from 44°C to 30°C.

C. Interconnections

The water caloric stimulator can be controlled by the computer-based CHARTR or MASTR ENG systems or by the N-500 strip-chart recorder. Connections are described in section IIIB (Rear Panel Connectors).

D. Charging the Memory Backup Capacitor

The NCI-480 incorporates a large capacitor to provide power to maintain the temperature and time setpoints while the unit is turned off. The operation of this capacitor is similar to that of a rechargeable battery.

1. **Before the NCI-480 is placed in service** - Although the capacitor is fully charged at the factory, considerable time may elapse before the unit is actually placed in service. Therefore, it is recommended that the following procedure be followed before the unit is placed in service.

   Turn the NCI-480 on. Open the chassis to turn off the pumps and heaters. Leave the NCI-480 turned on for at least 12 hours to fully charge the capacitor. The capacitor cannot be overcharged. A fully charged capacitor is expected to maintain the setpoints for two weeks or more.

2. **During routine use of the NCI-480** - The capacitor automatically charges whenever the unit is turned on. A couple of hours per day of routine use should be sufficient to keep the capacitor charged.

3. **After prolonged interruption of use** - If the NCI-480 is out of service for a week or more, follow the procedure for initial charging of the capacitor as described in "Before the NCI-480 is placed in service."

III. OPERATION

Safety, precision and operator convenience are the key design considerations for the NCI-480. Temperature control is provided for a body of water that includes the water in the delivery tube. By continuously circulating water through the delivery tube, the temperature throughout the system is maintained at the preset temperature. Flow rates and delivery times are precisely controlled as described below.

Centrifugal pumps move water from the selected bath through a valving system into the 10 ft. hose. The water passes through a tube in the hose into a special miniature two-way solenoid valve in the hand-held delivery head. Normally the water is routed back to the selected bath by means of a second tube in the hose. When stimulation is initiated, the miniature valve in the delivery head diverts the water from the return tube to the point of stimulation in the ear.

Temperature control is provided by balancing heat introduced by the heaters with heat loss in the baths and along the hose. High room temperatures (above 24°C) slow the stabilization of the temperatures in the baths. Continuous mixing insures that the temperature throughout the bath is uniform.

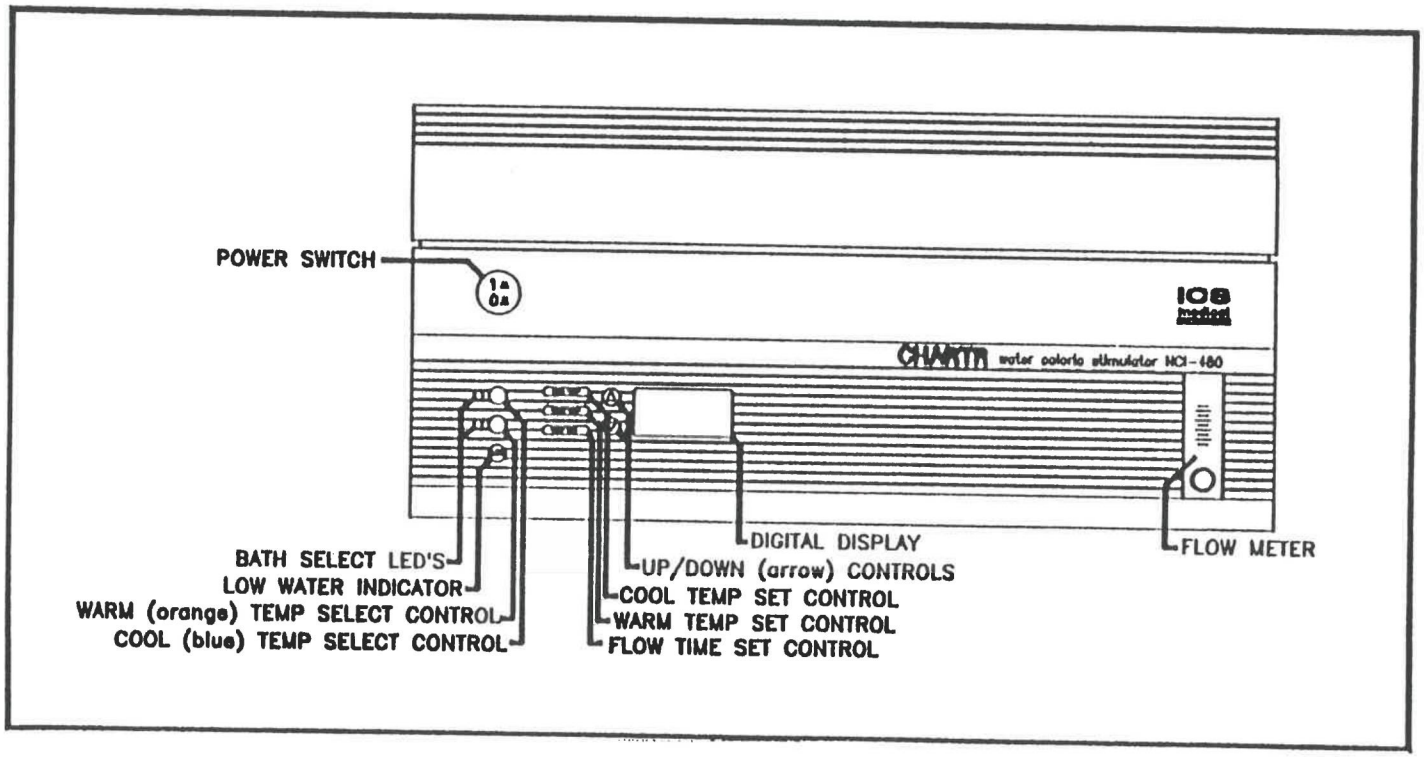

Figure 3: Front view of the NCI-480 showing panel controls.

A. Front Panel Controls

Figure 3 shows the front panel of the NCI-480. From this panel the operator can control temperature, length of stimulation and rate of flow.

1. Power Switch

This is a push on/push off type of switch that applies line power to the unit. Power-on is indicated by the illumination of the digital display.

2. Digital Display

The display usually shows the temperature of the selected bath. When the unit is first turned on, it selects the cool bath and displays that bath's temperature. When setting temperature or flow time, the display can show the "set" temperature for a warm or cool irrigation in degrees Celsius (indicated with a "C") or the flow time that is set (indicated in seconds with an "S").

3. Warm (orange) or Cool (blue) Temperature Select Controls

The warm or cool select buttons allow the operator to select the bath from which the water for stimulation will be drawn. The orange button selects warm; the blue button selects cool. The actual temperature of the selected bath is displayed and an LED illuminates next to the button used to select the bath. Once a bath is selected, it takes about 60 seconds for the entire recirculation system to come to equilibrium at the new temperature.

Selections made with these buttons can be used to override computer selections or remote selections from the N-500 recorder.

4. **Warm Temp/Cool Temp Set Controls**

These buttons provide a display of the "set" temperature and allow it to be changed. Pressing the **Warm Temp** button causes the set temperature for the warm bath to be displayed. The **Cool Temp** button presents the set temperature for the cool bath. Five seconds after pressing the **Warm Temp** or **Cool Temp** button or after making the last changes to set temperatures (see point 6 below), the display returns to the temperature of the selected bath.

5. **Flow Time Set Control**

This provides a display of the period of time for stimulation and allows it to be changed. By pressing the button marked **Flow Time**, the display changes to the current setting for flow time in seconds. Five seconds after pressing the button or making the last change (see point 6 below), the display returns to the temperature of the selected bath.

6. **Up or Down (arrow) Controls**

Once the **Warm Temp**, **Cool Temp** or **Flow Time** buttons have been selected, pressing the up or down (arrow) buttons will adjust the set temperature or the flow time. A single push of either the up or down button will increase or decrease the temperature by 0.1°C or the flow time by one second (the available time range is from 1 to 99 seconds). By holding the up or down button for more than 3/4 of a second, the temperature or the flow time will change at the rate of 3 units a second in the selected direction.

Once set, the operating parameters will be stored in memory registers so they will not need to be reentered each time the unit is turned on. The display will automatically return to the temperature of the selected bath 5 seconds after the last push of a button.

Tapping either bath select button (the blue or orange button), will immediately switch the display to that bath's temperature.

7. **Low Water Indicator**

If the water in either bath falls below a preset level, the low water indicator will illuminate to alert the user that more water needs to be added to the containers. (This will also light up if the top of the unit has not been properly secured; e.g. after cleaning the bath containers.) **If the user allows the water level in the baths to continue to drop once this indicator is illuminated, this will lead to imprecise control of the temperature in the baths and increased noise from the pumps.**

NOTE: When the unit is first turned on, the low water indicator will not light for a period of 2-3 minutes, even if the actual water level is too low.

8. **Flow Meter**

The flow rate can be adjusted by using the control at the base of the flow meter. While the flow meter is accurate, it is important to **regularly, preferably daily, test the rate of flow to assure that the proper amount of water is being utilized.** The flow meter should be set to deliver 500 cc/minute while actively stimulating. Set the top of the float in the flow meter to be in line with the 500 mark. (Recirculation flow is less than this, usually 300-400 cc/minute.)

B. Rear Panel Connectors

The rear panel is the location of connectors to external control or recording devices (Fig 4).

1. Computer Operation

The stimulator connects to a serial port on the computer or MCU of the CHARTR system via a standard 9-pin RS-232 data cable. The other end connects to the connector labeled **"computer"** on the rear panel of the stimulator itself. Through this connection to the computer, the computer is able to select a warm or cool stimulus through the software.

WARNING: If the connection to a computer is made, the computer should be turned on first before the NCI-480 is powered up. Failure to do so, may cause the NCI-480 to initiate flow if the computer is turned on afterwards.

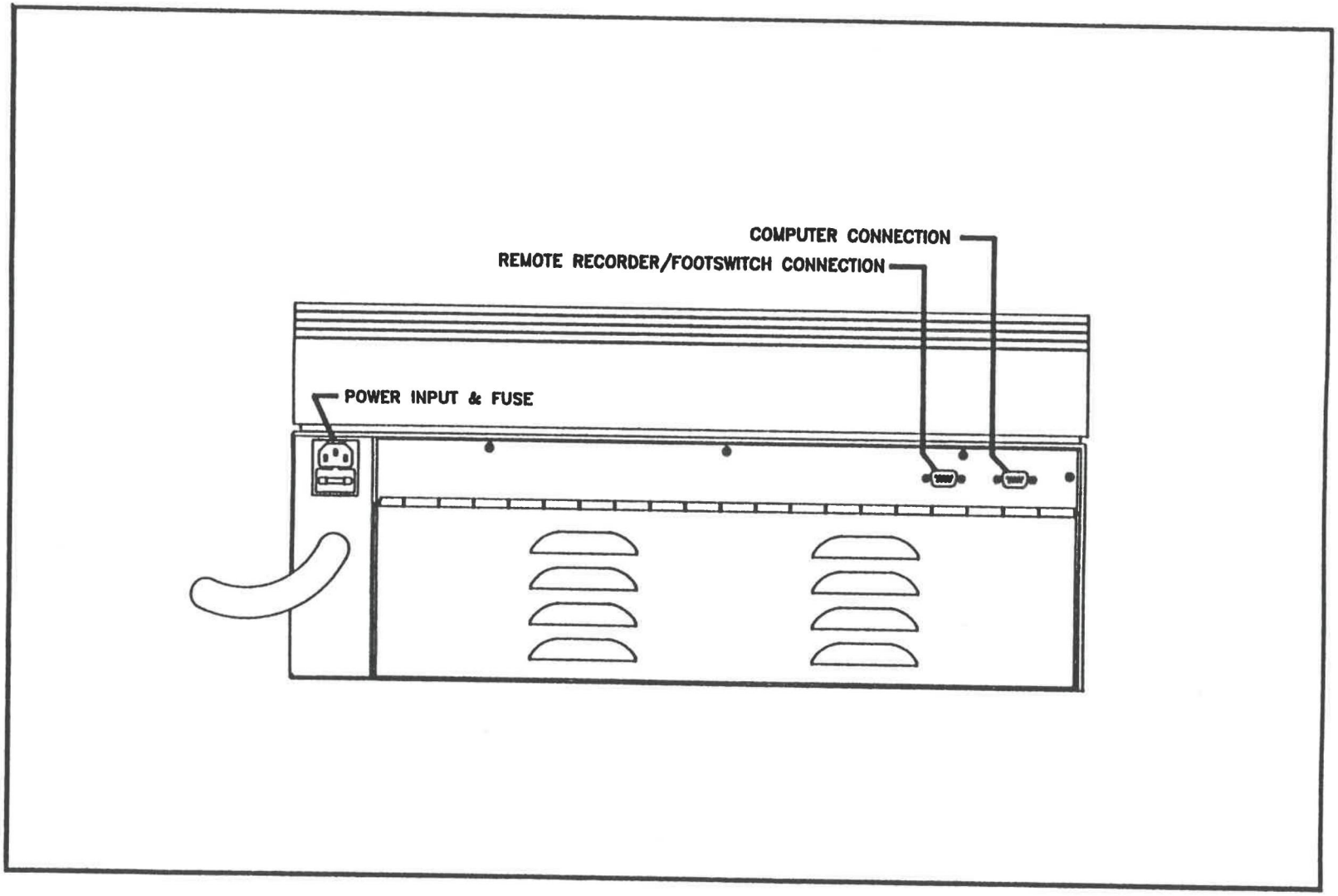

Figure 4: Rear panel view of the NCI-480 with connectors.

2. ICS Medical N-500 Recorder Operation

A cabling connection can be made between the connector labeled "**Remote**" at the rear of the stimulator and the eleven-pin connector at the rear of the recorder. This enables the user to select a warm or cool caloric test from the mode selection on the N-500's front panel. The warm or cool stimulus can also be selected from the front panel controls of the stimulator.

3. Remote Footswitch Connection

A footswitch can be connected to the connector labeled "**Remote**" at the rear of the stimulator. This would be used to activate the flow of water. If a computer is connected and a caloric test has been selected in the software, the first depression of the footswitch would initiate the flow of water and the recording, and subsequent depressions will center the tracing. The functions of the footswitch operate in parallel with the delivery switch on the delivery head.

C. The Delivery Head Controls

The delivery head (Fig 5) can be held any way that is comfortable for the user. The delivery switch starts the recording (if the connection to a computer is made) and initiates the flow of water if a warm or cool caloric test is selected. When the NCI-480 is connected to a computer, subsequent depressions of the switch remotely center the tracings.

A lamp to illuminate the patient's ear is incorporated into the delivery head. It is turned on and off by a pushbutton located on the delivery head below the delivery switch.

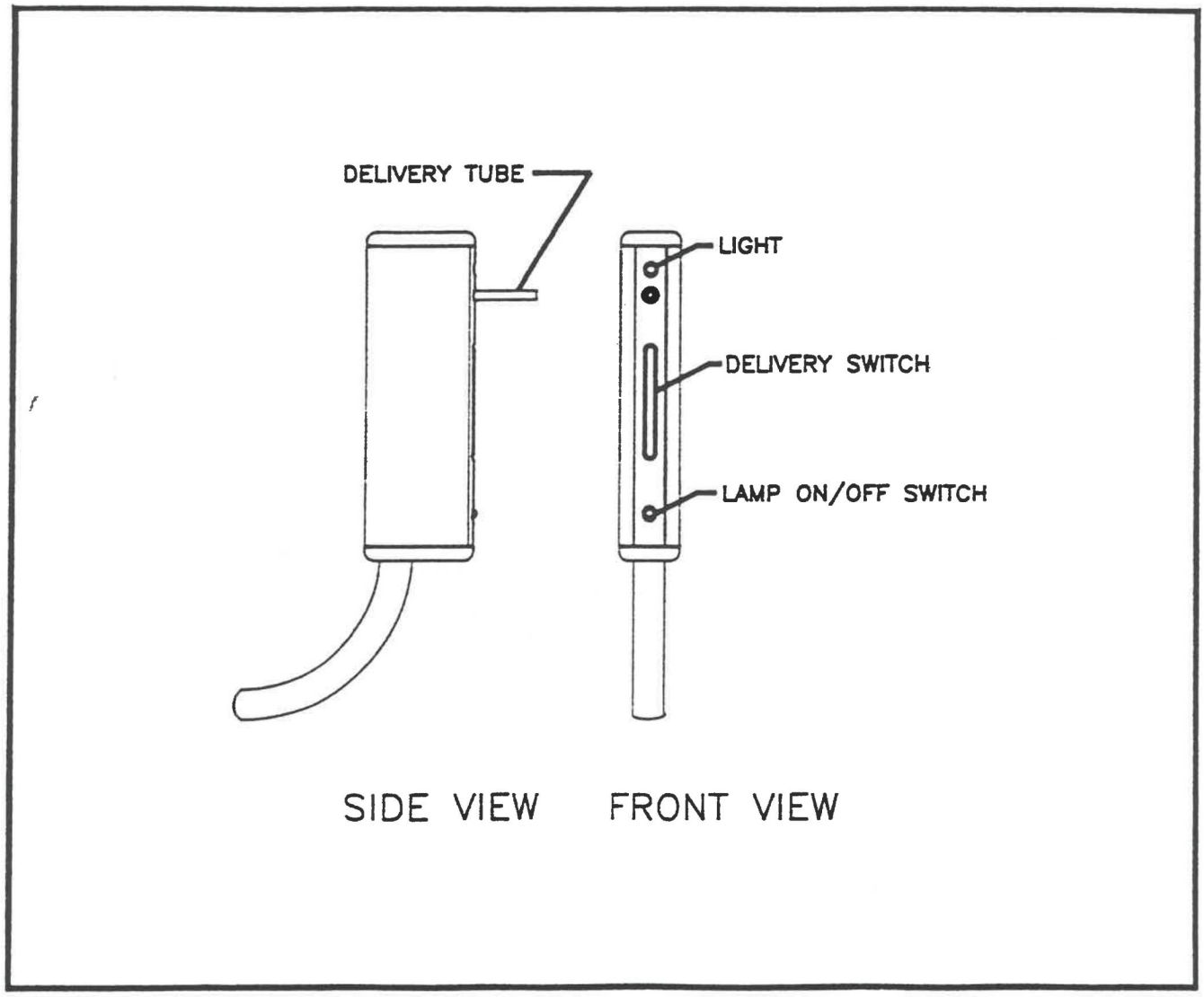

Figure 5: Front and side views of the NCI-480 delivery head and controls.

If the computer is turned on but the software is not running, flow can be activated by holding down the delivery switch for more than 3 seconds.

IV. OPERATING PROCEDURES

A. Preparation for Testing

Start by preparing the water baths. First insure that the power to the NCI-480 is turned off. Next, open the unit by lifting the chassis. Remove the bath containers and fill them with **distilled water** to the fill line (where the anti-splash return begins) and place them back in the unit. Carefully close the chassis.

The NCI-480 is now ready to use. Turn the unit on by pressing the green power switch at the top left of the front panel. **WARNING: If the NCI-480 is connected to a computer, the computer needs to be turned on <u>first.</u> Failure to do so, may cause the stimulator to initiate flow when the computer is turned on.**

Once powered on, the cool temperature bath will be automatically selected as indicated by the illumination of the green LED next to the blue bath select button. Press the orange bath select button if the warm bath is to be selected. The digital display will blink until the set temperature is reached. It takes approximately 20 minutes for set temperatures to be reached when the unit is first turned on. When a bath reaches its set temperature (± 0.25°C), the temperature display will stop flashing and illuminate steadily. Note that the flashing display does

not preclude the user from stimulating the ear. If the set temperature or flow time needs to be changed, see Section IIIA for instructions on how to use the front panel controls.

B. Testing Procedure

Otoscopically examine the external ear canal. It should be essentially free of cerumen. If it is not, cerumen must be removed prior to stimulating. Examine the tympanic membrane. **Do not stimulate if a perforation is suspected.**

Position a basin under the ear to collect the water from the stimulation. Have the patient close his eyes.

Position the tip of the delivery tube inside the ear canal and depress and release the start button on the delivery head. This initiates the flow of the water into the ear canal. If the stimulator is connected to the ENG CHARTR or MASTR systems, pressing the button on the delivery head will also start the recording and subsequent presses will center the tracing. If installed, the footswitch will also serve to start and center tracings and start the irrigation.

After the stimulation is complete, remove the delivery tip from the ear and carefully put the delivery head in its holder or in another safe receptacle. Be sure to utilize alerting tasks as the eye movements are being recorded.

V. SAFETY FEATURES

Complete patient and operator safety has been considered of the utmost importance in the design of the unit. For this reason, a heavy duty three-wire AC cable and "Hospital Grade" plug have been provided. **It is imperative that the instrument be properly grounded through this cable.** The round (third) pin of the plug is a

chassis ground which must be connected to a good earth ground. Where only a two terminal AC socket is available, it is permissible to use a three-wire to two-wire adaptor; however, the green lead of the adaptor, which makes contact with the ground pin of the cable, must be connected to a good ground such as a cold water pipe or electrical conduit pipe.

The NCI-480 has three fuses. The low amperage instrument fuse is located under the shroud on top of the unit. The high amperage heater and pump fuses are located on the rear panel alongside the power entry module. This fusing scheme is provided for added equipment and patient protection.

Another area of concern is separating water from electrical componentry. The NCI-480 positions all line voltage wiring and components in a chamber which is physically isolated from the water and tubing. Spillage of water or a break in tubing would not expose electrical components to water.

Should a failure occur which would cause the temperature of the bath to rise beyond safe limits, redundant safety features are provided. A temperature readout of the bath selected is always displayed. **Operators should always visually check the temperature of the bath before administering a test.** Precision solid-state temperature sensors, independent of the temperature meter, control the cycling of the heaters. Therefore, a malfunction of the meter will not create an overtemperature situation. To back up the whole system, an overtemperature circuit is provided. This shuts down the heating and pumping circuitry in the event of an overtemperature situation in either bath.

An interlock switch is incorporated to turn off the heaters and pumps when the chassis is opened. This feature offers the operator protection from accidental heater burns.

VI. MAINTENANCE

The electronic portion of the system requires no regular maintenance. However, it is necessary to clean the bath containers, heaters and pumps at least once a week.

Firstly, the use of anything other than pure distilled water in an NCI-480 can contribute to the accumulation of mineral deposits and particulate matter in the valves, pumps and tubing. This, in turn, can lead to the malfunction or failure of these components. Therefore, the use of anything other than pure distilled water will void the warranty on the NCI-480.

ICS Medical recommends cleaning the NCI-480 at least once a week. Soap and water should be used to wash the tubs, followed by a thorough rinsing. Use a wet cloth to wipe down the pumps and heaters.

As an occasional algae inhibiting treatment, fill the tubs with a mild bleach solution (one fluid ounce per gallon of distilled water) and run the unit for one-half hour, periodically switching from 30° to 44° and back. Empty the tubs and refill them with distilled water. Run the unit again, periodically switching from 30° to 44° and back. Empty the tubs. Refill with pure distilled water for clinical use.

Do not allow the NCI-480 to sit filled with water, unused, for extended periods of time. ICS Medical recommends that the chassis be lifted and left in the open position when the unit is not in use.

VII. WARRANTY

ICS Medical Corporation warrants this instrument to be free of defects in the material and workmanship for a period of one year from the date of shipment from the factory. Defects or deficiencies noted and brought to ICS Medical's attention during the warranty period will be corrected, or at ICS Medical's discretion, the instrument will be replaced. Should repairs require transportation to the factory, such shipments will be made prepaid.

Exempted from this warranty are the following:

A. Instruments not installed in accordance with the instructions in the manual.
B. Instruments serviced by personnel other than those authorized by ICS Medical.
C. Instruments involved in accidents or which have been misused or improperly maintained. This includes the use of water other than distilled water.

ICS Medical Corporation shall not be liable for consequential damages or other damages beyond the costs associated with the repair and/or replacement during the warranty period of defective instruments.

VIII. SPECIFICATIONS

Temperature range: 25° to 50°C
Cool stimulus: 25° to 37°C (Recommended setting: 30°C)
Warm stimulus: 37° to 50°C (Recommended setting: 44°C)

Temperature readout: Digital

Temperature accuracy: ±0.1°C

Time range: 1-99 seconds (Recommended setting: 30 seconds)

Flow rate range: 0-600 cc/minute (Recommended setting: 500 cc/minute)

Flow repeatability: ±1%

Remote control capability: Standard for both computer-based and recorder-based systems.

Input power: 120 VAC @ 60Hz or 240 VAC @ 50 Hz

Current: 10 A @ 120 VAC, 5 A @ 240 VAC

Safety: Over-temperature protection on main circuit. Over-temperature protection on secondary circuit. Temperature sensor failure shut down. Interlock switch disables heaters and pumps when opened.

Flow activation: Switch on delivery head or footswitch.

Size: (W x D x H) 22.5 x 17.5 x 11.5 inches
57 x 44 x 29 centimeters

Weight: 65 lbs. filled, 35 lbs. empty
30 kg. filled, 16 kg. empty